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House Committee on Oversight and Government Reform
"Safe and Affordable Biotech Drugs – The Need for a Generic Pathway"
Monday, March 26, 2007

Good morning Chairman Waxman, Ranking Member Davis and Members of the Oversight and Government Reform Committee. I am delighted to have the opportunity to testify before your Committee. The focus of my discussion will be the role of small innovator biotechnology companies in the current debate regarding the development of a regulatory pathway for approving biogeneric drugs.

I currently serve as the Chief Executive Officer of Insmed Incorporated. Insmed is a small biotechnology company focused on the development and commercialization of drugs for the treatment of metabolic and endocrine disorders where there are clear unmet medical needs. We received FDA approval for our lead product IPLEX at the end of 2005. IPLEX is a biologic, which is approved for the treatment of children suffering from a rare growth disorder. We are continuing to develop IPLEX for several major medical illnesses such as myotonic muscular dystrophy and medical complications associated with HIV infection.

I am here today to talk about biogeneric drug development and the regulatory path forward. I believe our experience with IPLEX is very illustrative of the scientific and technical issues confronting biogeneric drug developers, issues such as comparability testing and the nature and extent of clinical trials needed to support characterization of a generic biologic. Our experience tells us that these issues can be addressed using a sound, readily available scientific approach.

Insmed has developed significant intellectual capital focused towards protein characterization and purification. We have invested in building the facilities required to manufacture quality proteins. The biogenerics business is a business in which we would like to specialize. The combination of our proprietary protein platform with a biogeneric protein platform meets our goal to sustain innovation along with the ability to provide safe and affordable drugs to address a growing economic issue.

It is my belief that there are a number of my colleagues in similar size companies that are also interested in providing the scientific expertise to meet the challenges of producing biogenerics. I believe that I am representing the interests of many smaller biotechnology companies and large contract manufacturing companies. I believe H.R.1038 provides for a fair balance between rewarding innovation and creating a timely approval pathway and

The proposal introduced by Chairman Waxman is extremely appealing as a next step in stimulating competition in order to address an ever growing economic problem facing our healthcare system. Based on our company's experience with the FDA during the approval process of IPLEX, I am confident that the Waxman legislation is based on sound science and progressive insight into where the market should be in the coming years. Thank you again for this unique and important opportunity to share my experience and views. I look forward to your questions.